K070802

LERADO CHINA LIMITED
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TEL: +886-5-2475629 FAX: +886-5-2379672 website:http://www.lerado.com/

510(k) Summary

APR 13 2007

Device

Trade name: **LERADOTECH SC scooter**

Common name: **Electrical scooter**

Classification name: **Motorized three-wheeled vehicle**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3800**

Product Code: **89INI**

Classification: **Class II**

Predicate devices

AVANTICARE SA4022(K051538)/ LERADO CHINA LIMITED

Intend use of device

LERADOTECH SC scooter is intended for an indoor/outdoor scooter that provides transportation for disabled or elderly persons limited to a seated position.

Device description:

The **LERADOTECH SC** scooter is an indoor/outdoor transportation vehicles which is battery operated. The movement of the scooter is controlled by a tiller handle and a **thumb operated potentiometer throttle control lever** to engage and disengage the scooter motion in both the forward and reverse directions.

Substantial equivalence:

The **LERADOTECH SC scooter** is substantially equivalent to the **AVANTICARE SA4022 (K051538)** manufactured by **LERADO CHINA LIMITED.**

There are minor differences in performance specifications of the scooters, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **LERADO CHINA LIMITED** believes that the **LERADOTECH SC** scooter is substantially equivalent to legally marketed devices currently in commercial distribution.

(Continuous) Table 6-1 The substantial equivalence comparison of the LERADOTECH SC and SA4022

	SA4022(K051538)	LERADOTECH SC
Operation mode	Thumb operated potentiometer throttle control lever	
Battery	Lead-Acid 12V × 36AH × 2PCs	Lead-Acid 12V x 75AH × 2PCs
Battery level indicator	Yes	
Charger	HP 24V 3/5AMP (Automatic Type) off-board	HP 24V, 5 AMP (Automatic Type) off-board
Front wheel	10" × 2" foam filled tire × 2 PCs Rim: aluminum alloy	13" x 5" pneumatic tire × 2 PCs
Bumpers	Front/Rear: It's constructed by engineering plastics	Front: It's constructed by steel tube Rear: It's constructed by engineering plastics
Armrest	Yes, Foldable	
Tiller foldable	Yes	
Backrest recline	Yes	
Recline angle indicator	No	
Headrest	No	Yes
Height adjustable	No	Yes
Rear wheel	10" × 2" foam filled tire × 2 PCs Rim: aluminum alloy	13" x 5" pneumatic tire × 2 PCs
Break system	Intelligent regenerative electromagnetic brake	Intelligent regenerative electromagnetic brake and hand brake

Table 6-1 The substantial equivalence comparison of the LERADOTECH SC and SA4022

	SA4022(K051538)	LERADOTECH SC
Intended use	Three scooters are motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.	
Maximum loading	135 kg (300 lbs)	205 kg (450 lbs)
Overall height	980 mm (38.5")	1260 mm (50")
Overall length	1160 mm (45.7")	1370 mm (54")
Overall width	540 mm (21.3")	730 mm (29")
Seat overall height	520 mm (20.5")	
Seat overall width	457 mm (18")	
Seat overall depth	406 mm (16")	
Seat overall weight	15 kg (33 lbs)	
Motor output	350W x DC24V × 5100 RPM, 1PC	950W x DC24V × 1PC
Controller	Dynamic DS72K01	Dynamic DS16K01
Differential mechanism	Differential rate: 19.7 : 1	
Rear wheel drive	Sealed transaxle direct drive	

3.2 Performance standards

LERADOTECH SC scooter has been tested the applicable performance requirements specified in:

(1). ANSI/RESNA WC/Vol.1 section 1-1998 / ISO7176-1-1999 Determination of static stability

(2). ANSI/RESNA WC/Vol.1 section 6-1998 / ISO7176-6-2001 Determination of max speed, acceleration and deceleration of electric wheelchair

(3). ANSI/RESNA WC/Vol.2 section 21-1998 / ISO7176-21-2003 Requirements and test methods for electromagnetic compatibility of powered wheelchairs and motorized scooters

(4). CISPR 11-1990 Industrial, scientific and medical (ISM) Radio-Frequency equipment- electromagnetic disturbance characteristics – limits and methods of measurement

(5). IEC 61000-4-2-1995 EMC-Electrostatic discharge immunity test (ESD)

(6). IEC 61000-4-3-1995 EMC-Testing and measurement techniques-Radiated, RF, electromagnetic field immunity test

(7). California Bureau of Home Furnishings 116 Flammability Standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lerado China Limited
% Ms. Junnata Chang
14F-2, No. 1, Zhuangjing Road, Lane 25
Banqiao, Taipei County
China (Taiwan)

APR 13 2007

Re: K070802
Trade/Device Name: LERADOTECH SC scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: March 15, 2007
Received: March 23, 2007

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Device descriptive information

3.1 Statement of indication for use

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **LERADOTECH SC**

Indications for Use:

The **LERADOTECH SC** scooter is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X___

(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign
Division of Ge
and Neurolog

510(k) Number K070802

(Posted November 13, 2003)